

REMARKS

Entry of the foregoing amendment is respectfully requested.

Summary of Amendments

Upon entry of the foregoing amendment claim 55 is (editorially) amended, whereby claims 46-75 will continue to be pending, claims 46 and 64 being independent claims.

Summary of Office Action

As an initial matter, Applicants note with appreciation that the Examiner has withdrawn the finality of the previous Office Action and has issued a new non-final Office Action.

Claims 55 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for allegedly failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

Claims 46, 48 and 54-63 are newly rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Brunig et al., U.S. Patent No. 6,942,871 (hereafter “BRUNIG”) in view of Yu et al., U.S. Patent No. 5,571,841 (hereafter “YU”) and Niemiec et al., US 2002/0102295 A1 (hereafter “NIEMIEC”).

Claims 47 and 49-53 are newly rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over BRUNIG in view of YU, NIEMIEC and Diec et al., U.S. Patent No. 6,468,551 (hereafter “DIEC”).

Claims 46, 54, 55, 64, 66 and 72-75 are newly rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Guskey et al., U.S. Patent No. 5,776,494 (hereafter "GUSKEY") in view of BRUNIG and YU.

Claims 65 and 67-71 are newly rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over GUSKEY in view of BRUNIG, YU and DIEC.

Claims 46, 54-61, 63, 64 and 72-74 are newly provisionally rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over claims 34-57 of copending Application No. 10/574,231 in view of BRUNIG.

Response to Office Action

Reconsideration and withdrawal of the rejections of record are respectfully requested in view of the foregoing amendments and the following remarks.

Response to Rejection of Claim 55 under 35 U.S.C. § 112, Second Paragraph

Claim 55 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for allegedly failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention, due to being dependent from a claim of a higher numbering, i.e., claim 57.

Applicants submit that claim 55 has been amended to make it dependent from claim 54, thereby rendering this rejection moot.

Response to Rejections of Claims under 35 U.S.C. § 103(a) over BRUNIG as Primary Document

Claims 46, 48 and 54-63 are newly rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over BRUNIG in view of YU and NIEMIEC. Further, claims 47 and 49-53 are newly rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over BRUNIG in view of YU, NIEMIEC and DIEC. The rejections essentially allege that BRUNIG discloses or renders obvious all of the elements which are recited in the rejected claims with the exception of mandelic acid as the α -hydroxycarboxylic acid, the amount of the α -hydroxycarboxylic acid (which deficiencies are allegedly cured by YU and NIEMIEC) and an oil-in-water microemulsion which comprises an oil phase, a water phase and emulsifiers (which deficiency is allegedly cured by DIEC).

Applicants respectfully traverse these rejections. It is noted that the Examiner appears to take the position that because BRUNIG teaches that the microemulsion antiperspirant gel and stick preparations taught therein may contain antioxidants as optional components and α -hydroxy acids such as citric acid, lactic acid and malic acid are mentioned therein as members of a group of more than 100 examples of suitable antioxidants, one of ordinary skill in the art would be motivated by YU to use mandelic acid instead of citric acid, lactic acid or malic acid as α -hydroxy acid because all of these acids are mentioned in YU and YU allegedly also teaches that α -hydroxy acids such as, e.g., mandelic acid help enhance the efficacy of antiperspirants. The Examiner also appears to take the position that NIEMIEC teaches that mandelic acid is an antioxidant.

Applicants point out again that even if one were to assume, *arguendo*, that one of ordinary skill in the art would be motivated to incorporate an antioxidant and in particular, an α -hydroxy acid into the preparations of BRUNIG (although none of the

exemplified preparations of BRUNIG contains any antioxidant), YU fails to provide an apparent reason for one of ordinary skill in the art to use mandelic acid as an antioxidant and/or as an agent for enhancing the efficacy of the antiperspirants of BRUNIG.

In particular, while YU mentions that hydroxyacids and related compounds and additional compounds "can substantially enhance the therapeutic efficacy of cosmetic and pharmaceutical agents in topical treatment of cosmetic conditions, dermatological disorders or other afflictions" (col. 2, lines 15-21), it must not be overlooked that "antiperspirants" are only one of a host of most diverse examples of cosmetic and dermatological agents which are mentioned in col. 2, lines 24-40 of YU in this regard. Moreover, none of the Examples of YU relates to antiperspirants.

It further is noted that the claims of YU, although directed to the use of specifically and exclusively mandelic acid (which comes as a surprise in view of the fact that mandelic acid does not appear to be among the many acids which are employed in the numerous Examples of YU and is also not included in the list of the more than 30 "representative" hydroxyacids in col. 6, lines 23-25), do not recite the use of mandelic acid as an agent for enhancing the efficacy of any cosmetic or pharmaceutical agent in topical treatment of cosmetic conditions, dermatological disorders or other afflictions, but are drawn merely to the use of mandelic acid for visibly reducing a human wrinkle. This is a clear indication to one of ordinary skill in the art that mandelic acid does not belong to the hydroxyacids which are of value for enhancing the efficacy of any cosmetic or pharmaceutical agent, let alone of an antiperspirant.

In addition, YU mentions more than 50 specific examples of hydroxyacids of most diverse structures in columns 3-5 and 18/19 thereof. Yu also discloses a list of more

than 30 "representative" hydroxyacids in col. 6, lines 23-25, which list includes several derivatives of mandelic acid but not the parent compound itself.

In view of the foregoing facts it is apparent that it is only with hindsight that one can conclude that in view of the disclosure of YU one of ordinary skill in the art would have picked mandelic acid as an agent for enhancing the efficacy of the antiperspirants of BRUNIG.

Regarding the alleged antioxidant properties of mandelic acid, it is noted that the Examiner appears to rely on NIEMIEC, and in particular paragraphs [0087] and [0088] thereof. Applicants point out that while paragraph [0088] of NIEMIEC (which according to, e.g., the abstract thereof relates to compositions for skin or hair which contain a conditioning polymer encapsulated in a lipid vesicle and thus, has nothing to do with antiperspirants) mentions, among many others, antioxidants and alpha hydroxy acids (*inter alia*, mandelic acid), NIEMIEC does not teach that (all) alpha hydroxy acids are antioxidants. This becomes clear from the subsequent paragraph [0089] of NIEMIEC wherein both anti-oxidants and alpha-hydroxy acids are mentioned as examples of anti-aging agents, which would not make sense if the term "antioxidants" encompassed (all) alpha-hydroxy acids.

It further is pointed out again that the specific examples of α -hydroxy acids which are mentioned in BRUNIG as suitable antioxidants for optional incorporation into the compositions of BRUNIG, i.e., citric acid, lactic acid or malic acid, all are aliphatic acids whereas mandelic acid is an aromatic acid. Moreover, also in contrast to mandelic acid,

citric acid, lactic acid and malic acid all are employed in one or more of the Examples of YU.

Additionally, even if one were to assume, *arguendo*, that one of ordinary skill in the art would be motivated to add mandelic acid to the preparations of BRUNIG for any reason, it is not seen what would motivate him or her to optimize the ratio of antiperspirant agent and mandelic acid (see dependent claims 56 and 57). In this regard, the Office essentially argues (see page 7, first paragraph of the present Office Action) that BRUNIG teaches a concentration of antiperspirant active ingredients of 5-40 % by weight and YU teaches a concentration of hydroxy acids of from 0.01 to 99 % by weight, resulting in the (extremely broad) range of ratios of antiperspirant active ingredients (a) to alpha-hydroxycarboxylic acids (b) of from 4,000 : 1 (40 : 0.01) to about 1 : 20 (5 : 99), which encompasses the ranges recited in claims 56 and 57, i.e., from 15 : 1 to 1 : 1 and from 10 : 1 to 2.5 : 1, respectively. The Office also appears to argue that one of ordinary skill in the art could, for example, use a ratio (a) : (b) of 1 : 1, without giving any explanation why, let alone providing evidence that, using this ratio would be obvious to a person of ordinary skill in the art. In this regard, it is noted that none of the documents cited by the Examiner appears to disclose any specific composition which comprises both an antiperspirant and an alpha-hydroxycarboxylic acid and thus, there is no disclosure in this regard at all.

It additionally is pointed out again that dependent claim 55 recites, *inter alia*, that the one or more antiperspirant active ingredients of the claimed cosmetic formulation comprise aluminum chlorohydrate and/or activated aluminum chlorohydrate.

In comparison, the highly viscous microemulsion antiperspirant preparations of BRUNIG must contain aluminum-zirconium salts. See, e.g., abstract, col. 1, lines 13-17, col. 2, lines 2-6, col. 7, lines 40-62 and claim 1 of BRUNIG. BRUNIG neither teaches nor suggests that the aluminum-zirconium salts taught therein can be replaced by "pure" aluminum salts. On the contrary, a comparison of the compositions of Example 1 and Comparative Example C1 in Table 1 of BRUNIG shows that replacing an aluminum-zirconium salt by the same amount of aluminum chlorohydrate dramatically reduces the viscosity of the resultant antiperspirant microemulsion, i.e., from 825,000 mPas to 6,000 mPas. Since the antiperspirant microemulsions of BRUNIG are to be highly viscous with a viscosity of at least about 100,000 mPas (see, e.g. abstract and claim 1 of BRUNIG) BRUNIG not only fails to render obvious a microemulsion which comprises (activated) aluminum chlorohydrate but even teaches away therefrom.

It is noted that the present Office Action does not appear to contain any response to the above arguments.

Applicants submit that for at least all of the foregoing reasons, BRUNIG in view of YU, NIEMIC and DIEC is unable to render obvious the subject matter of any of the rejected claims. Accordingly, withdrawal of the present rejections under 35 U.S.C. § 103(a) over these documents is warranted and respectfully requested.

It further is pointed out that in view of the clear facts set forth above, Applicants have refrained from commenting on each and every allegation which is set forth in the present Office Action. Applicants' silence in this regard should however, by no means be construed as admission that any of the remaining allegations which are not addressed above are meritorious.

Response to Rejections of Claims under 35 U.S.C. § 103(a) over GUSKEY as Primary Document

Claims 46, 54, 55, 64, 66 and 72-75 are newly rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over GUSKEY in view of BRUNIG and YU. Further, claims 65 and 67-71 are newly rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over GUSKEY in view of BRUNIG, YU and DIEC. The rejections essentially allege that GUSKEY teaches or renders obvious all of the elements of the rejected claims with the exception that GUSKEY does not exemplify a combination of antiperspirant and mandelic acid and also fails to teach a formulation in the form of a microemulsion, which deficiencies are allegedly cured by BRUNIG and YU. The Office also concedes that GUSKEY fails to teach an oil-in-water microemulsion which comprises an oil phase, a water phase and emulsifiers and alleges that this deficiency is cured by DIEC.

These rejections are respectfully traversed as well. In particular, it is pointed out that the present claims are drawn to compositions comprising microemulsions, which microemulsions comprise, *inter alia*, one or more antiperspirant active ingredients.

The presence of a microemulsion (e.g., an O/W microemulsion as recited in, e.g., dependent claims 65 and 67) necessarily requires the presence of significant amounts of

water. In contrast, GUSKEY calls for the use of an anhydrous liquid carrier in the pharmaceutical compositions taught therein (see, e.g., col. 3, line 30 and end of claim 1 of GUSKEY), which renders the presence of a (micro)emulsion in the compositions of GUSKEY impossible. In this regard, it is noted that the mere fact that in the paragraph bridging pages 14 and 15 of GUSKEY the possible presence of emulsifiers in the (anhydrous) compositions taught therein is mentioned does not mean that the corresponding compositions are emulsions. Apparently, emulsifiers (surfactants) may also be useful in non-aqueous (e.g., alcoholic, etc.) systems.

In addition, in col. 7, lines 30-45 thereof, GUSKEY teaches that the antiperspirant actives are present in particulate form, preferably having an average particle size of about 5-200 microns. It is not seen that a (micro)emulsion which comprises one or more antiperspirant active ingredients can comprises these ingredients in particulate form.

Applicants submit that for at least all of the foregoing reasons, GUSKEY not only fails to render obvious the subject matter of the rejected claims, but even teaches away therefrom. It further is not seen that any of BRUNIG, YU and DIEC can cure the noted deficiencies.

It should also be pointed out that while GUSKEY mentions both antiperspirant active ingredients such as aluminum and aluminum-zirconium compounds and (alpha)-hydroxy acids such as, e.g., mandelic acid as examples of the many possible components of the compositions taught therein, hydroxy acids are taught in GUSKEY as examples of exfoliants. Applicants are unable to see what would motivate one of ordinary skill in the art to provide an antiperspirant (usually used in the armpit) which also acts as an

exfoliant. This is yet another reason why GUSKEY is unable to render obvious the subject matter of any of the rejected claims.

Applicants submit that for at least all of the foregoing reasons, GUSKEY in view of BRUNIG, YU and DIEC fails to render obvious the subject matter of any of the rejected claims. Accordingly, withdrawal of the present rejections under 35 U.S.C. § 103(a) over these documents is warranted and respectfully requested as well. In this regard, Applicants note that while the Examiner has not rejected (for good reasons) claims 47-53 and 56-63, all of which ultimately depend from claim 46, over GUSKEY in view of BRUNIG, YU and DIEC, claims which ultimately depend from independent claim 64 and correspond to some of claims 47-53 and 56-63 are rejected over these documents, which appears to be inconsistent.

It is pointed out that in view of the clear facts set forth above Applicants have refrained from commenting on each and every allegation which is set forth in the present Office Action. Applicants' silence in this regard should however, by no means be construed as admission that any of the remaining allegations which are not addressed above are meritorious.

Response to Provisional Rejection of Claims

Claims 46, 54-61, 63, 64 and 72-74 are newly provisionally rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being

unpatentable over claims 34-57 of copending Application No. 10/574,231 in view of BRUNIG.

Applicants respectfully disagree with the Examiner in this regard. At any rate, Applicants respectfully request that this rejection be held in abeyance until the Examiner has indicated allowable subject matter. Applicants will then decide whether the filing of a terminal disclaimer is appropriate.

CONCLUSION

In view of the foregoing, it is believed that all of the claims in this application are in condition for allowance, which action is respectfully requested. If any issues yet remain which can be resolved by a telephone conference, the Examiner is respectfully invited to contact the undersigned at the telephone number below.

Respectfully submitted,
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/Heribert F. Muensterer/

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December 11, 2009
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